Sodium

No. 2023/02Je, The Hague, February 7, 2023

Background document to the advisory report:
Dutch dietary guidelines for people with atherosclerotic cardiovascular disease
No. 2023/02e, The Hague, February 7, 2023

Health Council of the Netherlands

Contents

1 Introduction

This background document belongs to the advisory report *Dutch dietary guidelines for people with atherosclerotic cardiovascular disease* (ASCVD).[1] It describes the methodology for the search, selection and evaluation of the literature regarding the relationship between sodium consumption and health outcomes in people with ASCVD. It also describes the scientific evidence on this topic and the conclusions that have been drawn by the council's Committee on Nutrition.

1.1 Sodium

This background document describes the scientific evidence regarding sodium intake. Sodium is present in many foods and is added to foods. An important source of sodium in our food is table salt. Table salt (in Dutch: keukenzout) is the name given to the sodium chloride that is present in our food through use in the kitchen or at the dinner table, or because it is added to processed foods.[2] Sodium chloride consists for 40% (w/w) of sodium (and 60% of chloride); one gramme of table salt is equivalent to approximately 400 mg of sodium.[4] Sodium is also added to foods in other forms, such as sodium bicarbonate in baking soda and sodium lactate in cold cuts. A relatively small amount of sodium is naturally present in foods. Of the total sodium content of the diet, approximately 20% is added in the kitchen or at the table and about 80% is in foods as purchased. Foods often high in sodium are bread, cheese, sausages, hearty snacks and ready-to-eat products.

1.2 Sodium recommendation and intake in the Netherlands

The Health Council of the Netherlands included a guideline for table salt in the *Dutch dietary guidelines 2015*, which is as follows: Limit salt intake to 6 grammes daily.[3] This is equivalent to 2400 mg sodium.

Based on the sodium excretion in a 24-hour urine sample,[ab] median sodium intake in the Netherlands between 2012 and 2016 was estimated to be 9.7 g/d (interquartile range (IQR): 7.7-12.6 g/d) for men and 7.4 (5.7-9.0) g/d for women.[4]

[a] Estimating sodium intake by measuring sodium excretion in 24-hour urine collections is considered more valid than via dietary assessment methods such as 24-hour recalls or food frequency questionnaires.

[b] In the Netherlands, nutritional status surveys (i.e. monitoring intake of minerals via 24-hour urine samples) are collected periodically. In 2015, a nutritional status survey was conducted in 289 adults aged 19 to 70 years from Doetinchem, who collected urine once for 24 hours.[4] Because approximately 95% of daily sodium intake is excreted via urine, urinary sodium excretion was multiplied by 100/95.

2 Methodology

2.1 Questions

The Committee aimed to answer the following question: What is the relationship (effect or association) of relatively higher sodium intake compared to relatively lower sodium intake with health outcomes in people with ASCVD?

2.2 Target group

The target group of the current advisory report is people with ASCVD. The Committee defines this group as people with clinically established coronary heart disease (CHD, consisting of acute coronary syndromes [myocardial infarction and unstable angina], stable angina and revascularisation procedures such as percutaneous coronary intervention [PCI] and coronary artery bypass grafting [CABG]), peripheral arterial disease (PAD) or cerebrovascular disease (consisting of stroke and transient ischemic attack). In the target population, atherosclerosis in the coronary arteries, aorta, iliac and femoral arteries, and cerebral arteries is the main underlying pathological process. Groups with a high risk (but no manifestation) of ASCVD, such as people with hypertension or elevated LDL cholesterol levels, fall outside this definition. Also, the target group of this advice does not include people with heart failure (except when those people also suffer from ASCVD). A detailed description of the target group of this advisory report is provided in the background document *Methodology for the evaluation of the evidence*.[5]

The Committee also considered studies performed in people with cardiovascular disease (CVD) in general (not further specified), under the assumption that the majority of this population will have ASCVD.

2.3 Nutritional topics

The Committee searched for studies into the effect or association of sodium intake with health outcomes.

In addition, the Committee preferred to include cohort studies in which sodium intake was measured after the occurrence of the ASCVD event, and preferably at least 6 months after the event in order to capture the habitual post-event intake and long-term effects of this exposure, since people may change their sodium intake habits because of an ASCVD event.

2.4 Health outcomes

The Committee selected the following health outcomes for this advisory report (further explained in the background document *Methodology for the evaluation of the evidence*[5]):

- short-term surrogate outcomes:
  - body weight
  - systolic blood pressure
  - low-density lipoprotein (LDL) cholesterol
  - estimated glomerular filtration rate (eGFR)
  - glycated haemoglobin (HbA1c) and fasting blood glucose
- long-term health outcomes:
  - all-cause mortality
  - morbidity and/or mortality from total CVD, CHD, stroke (cerebrovascular disease), heart failure, atrial fibrillation, type 2 diabetes, chronic obstructive pulmonary diseases (COPD), total cancer, breast cancer, colorectal cancer, lung cancer, dementia, depression
  - subtypes of CHD, such as myocardial infarction, angina pectoris and revascularisation procedures (i.e., coronary artery bypass surgery and percutaneous coronary intervention)

For cohort studies, the Committee included only studies in the above-described category named long-term health outcomes.

2.5 Selection and evaluation of the literature and drawing conclusions

2.5.1 Search and selection of studies

A detailed description of the approach used by the Committee for selecting and evaluating the scientific literature is provided in the background document *Methodology for the evaluation of the evidence*.[5] In short, the Committee aimed to base its evaluation of scientific literature on systematic reviews (SRs), including meta-analyses (MAs) and pooled analyses, of randomised controlled trials (RCTs) and/or prospective cohort studies examining the relationship of sodium intake with the above-mentioned health outcomes in people with ASCVD. To identify such publications, the Committee searched PubMed and Scopus in June 2021. No relevant SRs and/or MAs were found. An additional literature search was performed to select individual RCTs and cohort studies. To this end, the Committee searched PubMed and Scopus in July 2021. This yielded one RCT and one cohort study relevant for the Committee's evaluation.[6,7] The search strategy and specification of the study selection are presented in Annex A. In

addition, the reference lists of the publications and articles that cited the two included studies were checked, which yielded no additional relevant publications. In addition, existing guidelines for people with ASCVD were checked, which also did not yield extra publications.

2.5.2 Drawing conclusions

A detailed description of the approach used for drawing conclusions is provided in the background document *Methodology for the evaluation of the evidence*.[5] In short, the Committee drew conclusions on (the certainty of) the evidence regarding the associations of sodium intake with risk of health outcomes in people with (prior) ASCVD, based on the number of studies, the number of participants and the number of cases that contributed to the evaluation. Also, it took the quality of the studies, in particular the risk of bias, and the heterogeneity between studies into account. The Committee used the decision tree (presented in the background document *Methodology for the evaluation of the evidence*[5]) as a tool to support consistency in drawing conclusions.

3 Effects and associations of sodium intake

In this chapter, the Committee describes the scientific evidence for effects and associations of sodium intake with health outcomes in people with ASCVD.

3.1 RCTs

Conclusion:
There is too little research from intervention studies to draw a conclusion on the effect of sodium intake on the risk of stroke in people who experienced a previous stroke.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:
There is one RCT, by Neal et al.[6] (2021), that was performed in a high (cardiovascular) risk population (n=29995), of whom 73% (n=15242) had experienced a stroke prior to study inclusion. The study was performed in China. The intervention group received a salt substitute (75% sodium chloride and 25% potassium chloride by mass). The control group used regular salt (100% sodium chloride). More than 5000 participants (2599 in the intervention group and 2998 in the control group) in the stroke survivors experienced a subsequent stroke during a mean follow-up of 4.7 years. People in the intervention group had a lower (subsequent) stroke risk than those in the control group (rate ratio [RR] 0.86 (95% confidence interval [CI] 0.78, 0.95)).
In principle (according to the decision tree), the Committee judges that one study provides too little evidence to base conclusions on. However, the study included an exceptionally large number of participants and cases. Therefore, the Committee considered whether it could draw a conclusion from this study. The Committee judged that there is uncertainty about the generalisability of the findings to Dutch people. Therefore, the Committee did not take this study into account for the current advisory report. The uncertainty raised from the observation that the study was performed in China and specifically that the study participants had a particularly low potassium excretion in urine (compared to average Dutch people). Potassium was provided via the salt substitute, which brought the potassium excretion levels to a more ‘normal’ level. Since a low potassium intake is associated with increased CVD and mortality risk, the study results may (at least in part) be due to the potassium supplementation.[8,9]

3.2 Cohort studies

Only one study with a small sample size was identified for the outcomes total CVD, heart failure, MI and stroke and therefore this study is not described in detail below.

Conclusion:

There is too little research from cohort studies to draw conclusions on the associations of sodium intake with the risks of total CVD, heart failure, MI and stroke in people with CVD.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

There is one prospective cohort study that addressed the association between sodium intake and total CVD, heart failure, MI and stroke in people with CVD.[7] According to the decision tree, one study provides too little evidence to base conclusions on.

3.3 Summary of conclusions

The Committee's conclusions regarding the effects and associations of sodium intake with health outcomes in people with ASCVD are summarised in Table 1.

Table 1 Overview of conclusions regarding the effects and associations of sodium intake with health outcomes in people with ASCVD

Health outcome[a]	Study design	Conclusion
Stroke	RCT	Too little research
Total CVD	Cohort study	Too little research
Heart failure	Cohort study	Too little research
MI	Cohort study	Too little research
Stroke	Cohort study	Too little research

Abbreviations: ASCVD: atherosclerotic cardiovascular disease; CVD: cardiovascular disease; MI: myocardial infarction; RCT: randomised controlled trial.

[a] The table contains the health outcomes for which (relevant) studies were found. For the health outcomes that are not listed in the table, no (relevant) studies were found.

References

1 Health Council of the Netherlands. *Dutch dietary guidelines for people with atherosclerotic cardiovascular disease*. The Hague: Health Council of the Netherlands, 2023.

2 Gezondheidsraad. *Natrium. Achtergronddocument bij Richtlijnen goede voeding 2015*. Den Haag: Gezondheidsraad, 2015; publicatienummer A15/15.

3 Health Council of the Netherlands. *Dutch dietary guidelines 2015*. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/26E.

4 Hendriksen M, Etemad Z, Van den Bogaard CHM, Van der A DL. *Zout-, jodium- en kaliuminname 2015. Voedingsstatusonderzoek bij volwassenen uit Doetinchem*. Bilthoven: RIVM Briefrapport 2016-0081, 2015.

5 Health Council of the Netherlands. *Methodology for the evaluation of evidence. Background document to Dutch dietary guidelines for people with atherosclerotic cardiovascular disease.* The Hague: Health Council of the Netherlands, 2023.

6 Neal B, Wu Y, Feng X, Zhang R, Zhang Y, Shi J, et al. *Effect of Salt Substitution on Cardiovascular Events and Death*. N Engl J Med 2021; 385(12): 1067-1077.

7 Mills KT, Chen J, Yang W, Appel LJ, Kusek JW, Alper A, et al. *Sodium Excretion and the Risk of Cardiovascular Disease in Patients With Chronic Kidney Disease*. JAMA 2016; 315(20): 2200-2210.

8 Graudal N, Jurgens G, Alderman MH. *Salt Substitute and Cardiovascular Events and Death*. N Engl J Med 2021; 385(26): 2491-2492.

9 Zuccala G, Laudisio A, Ciaburri M. *Salt Substitute and Cardiovascular Events and Death*. N Engl J Med 2021; 385(26): 2492.

Annexes

Annex A Search strategy and study selection

A.1 Search strategy for systematic reviews and meta-analyses

PubMed

(Coronary disease [MeSH] OR Acute coronary syndrome [MeSH] OR Angina pectoris [MeSH] OR Coronary artery disease [MeSH] OR Myocardial infarction [MeSH] OR Peripheral arterial disease [MeSH] OR Intermittent claudication [MeSH] OR Stroke [MeSH] OR Brain ischemia [MeSH] OR Cerebrovascular disorders [MeSH] OR Percutaneous coronary intervention [MeSH] OR Coronary artery bypass [MeSH] OR Coronary disease [TIAB] OR Coronary heart disease [TIAB] OR Acute coronary syndrome [TIAB] OR Angina pectoris [TIAB] OR Angina [TIAB] OR Ischemic heart disease [TIAB] OR Ischaemic heart disease [TIAB] OR Coronary artery disease [TIAB] OR Coronary Arteriosclerosis [TIAB] OR Myocardial infarction [TIAB] OR Heart attack [TIAB] OR Peripheral arterial disease [TIAB] OR Peripheral vascular disease [TIAB] OR Intermittent claudication [TIAB] OR Stroke [TIAB] OR Acute stroke [TIAB] OR Cerebrovascular Apoplexy [TIAB] OR Apoplexy [TIAB] OR Ischemic stroke [TIAB] OR Ischaemic stroke [TIAB] OR Hemorrhagic stroke [TIAB] OR Haemorrhagic stroke [TIAB] OR Cerebrovascular accident [TIAB] OR Acute cerebrovascular accident [TIAB] OR Cerebrovascular stroke [TIAB] OR Brain vascular accident [TIAB] OR Brain ischemia [TIAB] OR Cerebral ischemia [TIAB] OR Cerebral stroke [TIAB] OR Brain accident [TIAB] OR Brain infarction [TIAB] OR Cerebral infarction [TIAB] OR Transient ischemic attack [TIAB] OR TIA [TIAB] OR Cerebrovascular* [TIAB] OR Subarachnoid haemorrhage [TIAB] OR Intracerebral hemorrhage [TIAB] OR Intracranial hemorrhages [TIAB] OR Coronary revascularization [TIAB] OR Percutaneous coronary intervention [TIAB] OR Coronary artery bypass graft surgery [TIAB] OR Percutaneous transluminal coronary angioplasty [TIAB] OR Percutaneous transluminal angioplasty [TIAB] OR Coronary angioplasty [TIAB] OR Atherosclerotic cardiovascular disease [TIAB] OR Carotid artery disease [TIAB] OR CHD [TIAB] OR ACS [TIAB] OR IHD [TIAB] OR CAD [TIAB] OR MI [TIAB] OR AMI [TIAB] OR PAD [TIAB] OR CVA [TIAB] OR CVAs [TIAB] OR TIA [TIAB] OR PCI [TIAB] OR CABG [TIAB] OR PTCA [TIAB] OR PTA [TIAB] OR ASCVD [TIAB])

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Scopus

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A.2 Search strategy for RCTs and cohort studies

PubMed

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A.3 Selection of individual RCTs and cohort studies

Step 1. Identification
3778 records retrieved:

- PubMed: 1670
- Scopus: 2108
- Other sources: 0

971 duplicates excluded

Step 2. Screening
2807 records screened,
2798 records excluded after first selection

Step 3. Eligibility
9 full-texts assessed,
7 records excluded after second selection due to:

- No exposure of interest: 2
- Different study population (<90% ASCVD): 5

Step 4. Inclusion
2 records included

- RCTs: 1
- Cohort studies: 1

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).
The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.
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